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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
JOHN P. DONOGHUE, MIJAIL D. SERRUYA,
J. CHRISTOPHER FLAHERTY, BRIAN W. HATT, and
JON P. JOSEPH

Appeal 2008-3744
Application 10/798,919
Technology Center 3700

Decided: September 8, 2008

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to systems and methods for predicting neurological events in patients' bodies. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1-15, 20-22, 26-39, 48-50, 54, 58-61, 63-77, 82-84, 88-99, 105-111, 115, and 119-126 stand rejected and are on appeal (App. Br. 7). Claims 1 and 64 are the independent claims on appeal. Claim 1 is representative and reads as follows:

> 1. A system for predicting occurrence of a neurological event in a patient's body, comprising:
>
> an implant configured to be placed in the body and detect signals indicative of an activity that precedes the neurological event;
>
> a processing unit configured to process the detected signals so as to predict the neurological event prior to the occurrence;
>
> a storage device containing a target signal indicative of the activity that precedes the neurological event, the target signal including one or more previously detected signals indicative of the activity that precedes the neurological event; and
>
> wherein the processing unit is configured to compare the detected signals with the target signal.

The Examiner applies the following documents in rejecting the claims:

Abraham-Fuchs et al.	US 4,974,602	Dec. 4, 1990
Fischell et al.	US 6,016,449	Jan. 18, 2000
Pless et al.	US 2003/0004428 A1	Jan. 2, 2003
Gliner	US 2003/0074032 A1	Apr. 17, 2003

The following rejections are before us for review:

Claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59-61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pless (Ans. 5-8).

Claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless in view of Abraham-Fuchs (Ans. 9-10).

Claim 107 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless or Pless in view of Abraham-Fuchs (Ans. 10).

Claims 22 and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless, or Pless in view of Abraham-Fuchs, in view of Gliner (Ans. 10-11).

ANTICIPATION

ISSUE

The Examiner finds that Pless describes an implantable device that meets all of the limitations of the rejected claims (Ans. 5-8). The Examiner notes that Pless incorporates Fischell into its disclosure by reference, and states that, despite reference to portions of the Fischell disclosure, "**all** listed claims are rejected under the Pless reference only" (*id.* at 5).

With respect to claim 1, the Examiner finds that Pless' implantable device has "a means to detect signals indicative of activity preceding an event (422) and a processing unit to predict a neurological event (428 and abstract)" (*id.*). The Examiner contends that "the event detection algorithm incorporated by Pless and disclosed by Fischell comprises storing a target signal indicative of activity preceding a neurological event, in the form of a threshold. Examiner is interpreting a threshold as a constant level signal that is inherently set by some previous signal" (*id.*). Moreover, the Examiner contends, "this threshold is compared to detected signals (Fig. 5A-5D) and is

indicative of an activity that precedes a neurological event (a 'fully-developed' epileptic seizure, see col. 5, line 4)" (*id.*).

Appellants contend that the Examiner erred in finding that Pless anticipates claim 1 because the Fischell disclosure incorporated into Pless has no explicit "teaching of the threshold including a *previously detected signal* indicative of activity that precedes a neurological event" (App. Br. 15), and because Pless/Fischell cannot be properly interpreted as inherently disclosing such a signal (*id.* at 16-18).

Appellants do not argue the claims subject to this ground of rejection separately. We select claim 1 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii). The issue with respect to this rejection, then, is whether the Examiner erred in finding that Pless' device meets all of the limitations in claim 1.

FINDNGS OF FACT ("FF")

1. Pless discloses "a system and method for detecting and predicting epileptic seizures and their onsets by analyzing electroencephalogram [(EEG)] and electrocorticogram [(ECoG)] signals with an implantable device" (Pless [0001]).

2. Pless states:

> U.S. Pat. No. 6,016,449 to Fischell, et al. (which is hereby incorporated by reference as though set forth in full herein), describes an implantable seizure detection and treatment system. In the Fischell system, various detection methods are possible, all of which essentially rely upon the analysis (either in the time domain or the frequency domain) of processed EEG signals. Fischell's controller is preferably implanted intracranially, but other approaches are also possible, including the use of an external controller. When a seizure is detected, the Fischell system applies responsive electrical

> stimulation to terminate the seizure, a capability that will be discussed in further detail below.

(Pless [0022].)

3. Pless' system uses "an implantable device . . . for detecting and predicting epileptic seizures [that] includes a relatively low-speed and low-power central processing unit, as well as customized electronic circuit modules in a detection subsystem" (Pless [0035]).

4. In processing detected EEG signals, Pless' device uses "two different data reduction methodologies, both of which collect data representative of EEG signals within a sequence of uniform time windows each having a specified duration" (Pless [0039]).

5. Pless discloses:

> The first data reduction methodology involves the calculation of a "line length function" for an EEG signal within a time window. Specifically, the line length function of a digital signal represents an accumulation of the sample-to-sample amplitude variation in the EEG signal within the time window. Stated another way, the line length function is representative of the variability of the input signal.

(Pless [0040].)

6. Pless discloses:

> The second data reduction methodology involves the calculation of an "area function" represented by an EEG signal within a time window. Specifically, the area function is calculated as an aggregation of the EEG's signal total deviation from zero over the time window, whether positive or negative. The mathematical analogue for the area function defined above is the mathematical integral of the absolute value of the EEG function (as both positive and negative signals contribute to positive area).

(Pless [0041].)

7. Pless describes the "detection subsystem" of its device as follows:

> [T]he detection subsystem also performs prediction, which in the context of the present application is a form of detection that occurs before identifiable clinical symptoms or even obvious electrographic patterns are evident upon inspection. The same methods, potentially with different parameters, are adapted to be used for both detection and prediction. Generally, as described herein, an event (such as an epileptic seizure) may be detected, an electrographic "onset" of such an event (an electrographic indication of an event occurring at the same time as or before the clinical event begins) may be detected (and may be characterized by different waveform observations than the event itself), and a "precursor" to an event (electrographic activity regularly occurring some time before the clinical event) may be detected as predictive of the event.

(Pless [0035].)

8. Pless discloses:

> The detection subsystem **422** includes an EEG analyzer function. The EEG analyzer function is adapted to receive EEG signals from the electrodes **412-418**, through the electrode interface **420**, and to process those EEG signals to identify neurological activity indicative of a seizure, an onset of a seizure, or a precursor to a seizure. One way to implement such EEG analysis functionality is disclosed in detail in U.S. Pat. No. 6,016,449 to Fischell et al., incorporated by reference above . . . .

(Pless [0088]; *see also* Figure 4.)

9. Fischell discloses an implantable device that uses "a multi-electrode array with sophisticated signal processing techniques to achieve reliable detection of the onset of a neurological event (such as an epileptic seizure or

migraine headache) typically originating from a focus of limited spatial extent within the brain" (Fischell, col. 2, ll. 42-46).

10. Fischell states that its device "provides means for generating an ensemble of coordinated electrical stimuli designed to terminate the neurological event immediately upon (or even prior to) its onset. Thus, the present invention is a responsive detection and stimulation system for the early recognition and prompt treatment of a neurological event" (Fischell, col. 2, ll. 52-57).

11. Fischell discloses that its device functions by detecting and processing electrical signals from the brain, and then comparing the processed signals to a threshold signal (Fischell, col. 19, ll. 3-50). Specifically, Fischell discloses that:

> If the amplitude of the sum of the time synchronized squared EEG signals **355** exceeds the event detection threshold **369** as shown in FIG. 5D (using threshold detector algorithm **368** of FIG. 7), the algorithm **368** sends a positive event detected message **358** to the event density counter/detector algorithm **371**. The event density counter/detector algorithm **371** determines if there have been enough events in the most recent time period "T" to notify the central processor **51** with the event identified message **372** indicating that an event has really occurred.

(Fischell, col. 19, ll. 4-12.)

12. Regarding the threshold, Fischell discloses that:

> The thresholds to be used for detection by the threshold detector algorithms **368** and **367-1** through **367-M** and the required event densities for event identification by the event density counter/detector algorithms **371** and **369-1** through **369-M**, will typically be programmed to minimize the chance of missing a "real" neurological event even though this could result in the occasional false positive identification of an event.

> This bias toward allowing false positives might typically be set to produce from 1/2 to 5 times as many false positives as "real" events.

(Fischell, col. 20, ll. 19-28.)

13. In another embodiment, Fischell discloses an "event detection subsystem **130** that uses time domain information for event detection. In this embodiment, analog circuitry **139** is used to process and detect possible neurological events, and digital logic circuitry **138** is used to check if the density of possible events is sufficient to declare a 'real' event" (Fischell, col. 23, ll. 47-52). In this embodiment incoming EEG signals are amplified, squared by squarer circuits, processed by analog delay circuits to adjust for the different locations of the electrodes, and then added together by a summing circuit (*id.* at col. 23, ll. 52-64).

14. Fischell discloses:

> The resulting summed time synchronized signal **125** is then fed into a threshold detection circuit **136** which will output a digital pulse **126** whenever the summed time synchronized signal **125** exceeds a pre-set threshold. The digital pulses **126** collected over time are then processed by the digital logic circuit **138** to determine if the event is real or not. The delay parameters **124**A through **124**N are input to the delay lines **133**A through **133**N from the central processor **151** and can be pre-set for a particular patient. Setting the values for these time delays could be based on measured delays of EEG signals received from an epileptic focus during diagnostic testing of the patient using the implanted system **10** of FIG. 2.

(Fischell, col. 23, l. 64, through col. 24, l. 9.)

15. In one embodiment, Pless discloses that it applies the EEG threshold analysis to its "line length function" data reduction methodology as follows:

"the accumulated total line length is compared to a dynamic threshold, which is based on a trend of recently observed line lengths" (Pless [0148]).

16. In one embodiment, Pless discloses that it applies the EEG threshold analysis to its "area function" data reduction methodology as follows: "the accumulated total area is compared to a dynamic threshold, which is based on a trend of recently observed areas" (Pless [0161]).

PRINCIPLES OF LAW

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). During examination, the PTO must interpret terms in a claim using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

We agree with the Examiner that Pless meets all of the limitations of claim 1. Pless discloses "an implantable device . . . for detecting *and predicting* epileptic seizures [that] includes a relatively low-speed and low-power central processing unit, as well as customized electronic circuit modules in a detection subsystem" (Pless [0035] (FF 3) (emphasis added)). Pless' system therefore meets the limitations in claim 1 with respect to the implant, the processor, and the capacities to detect and process signals preceding a neurological event.

The "detection subsystem" of Pless' device performs the task of predicting epileptic seizures by detecting a "'precursor' to an event," which is characterized as "electrographic activity regularly occurring some time before the clinical event" (Pless [0035] (FF 7)). Incorporating Fischell in its entirety by reference (FF 2), Pless discloses that its detection subsystem includes Fischell's EEG analysis functionality "to identify neurological activity indicative of a seizure, an onset of a seizure, *or a precursor to a seizure*" (Pless [0088] (FF 8) (emphasis added)).

Fischell in turn discloses that its device uses multiple electrodes to detect neurological events, such as epileptic seizures (*see* FF 8, 9), with the objective of "terminat[ing] the neurological event immediately upon (*or even prior to*) its onset. Thus, the present invention is a responsive detection and stimulation system for the early recognition and prompt treatment of a neurological event" (Fischell, col. 2, ll. 52-57 (FF 10) (emphasis added)).

Fischell discloses that its device functions by processing electrographic signals from the brain and comparing them to a preset threshold to determine whether an actual neurological event, such as a seizure, is occurring or is about to occur (FF 9-14). Because Pless' device uses the preset threshold signal EEG analysis disclosed by Fischell to indicate whether electrographic activity detected by the device in fact precedes a seizure, we agree with the Examiner that Pless' device meets the limitation in claim 1 requiring the storage device to have "a target signal indicative of the activity that precedes the neurological event."

With respect to the disputed limitation, the Examiner contends that Pless, by incorporating Fischell, inherently meets the limitation requiring the target signal to "includ[e] one or more previously detected signals indicative

of the activity that precedes the neurological event." Specifically, the Examiner urges that because Fischell uses previously detected EEG signals to determine the delay values for processing subsequently detected EEG signals, the target threshold necessarily includes previously detected signals indicative of activity preceding a seizure (*see, e.g.,* Ans. 3 (citing Fischell col. 24, ll. 6-9) (FF 13-14)). The Examiner also urges that, because Fischell sets the threshold relatively low to bias the detection toward false positives, one must necessarily have detected signals previously, in order to be able to distinguish between an event and a non-event (Ans. 11 (citing Fischell col. 20, ll. 19-28) (FF 12)).

Appellants argue that the Examiner's interpretation of Pless/Fischell is erroneous because the target threshold can be set arbitrarily low without inherently including a previously detected signal (*see, e.g.* App. Br. 16-18; *also* Reply Br. 2-6). Moreover, Appellants argue, the time delays of Fischell involve correcting the different propagation times required for the signal to travel from the epileptic focus to the various electrodes, and are therefore not necessarily previously detected signals indicative of activity that precedes a neurological event (Reply Br. 4-5).

Appellants' arguments do not persuade us that Pless fails to meet claim 1's limitation requiring the target signal to "includ[e] one or more previously detected signals indicative of the activity that precedes the neurological event." Specifically, Pless discloses that its device uses "line length function" and "area function" data reduction techniques when analyzing EEG data (FF 4-6).

Pless further discloses that when it applies these techniques to the threshold detection methodology incorporated from Fischell, "the

accumulated total line length is compared to a dynamic threshold, *which is based on a trend of recently observed line lengths*" (Pless [0148] (FF 15) (emphasis added)), and "the accumulated total area is compared to a dynamic threshold, *which is based on a trend of recently observed areas*" (Pless [0161] (emphasis added)). Thus, because Pless bases its threshold detection methods on recently observed signals, we agree that Pless' storage device contains "a target signal including one or more previously detected signals indicative of the activity that precedes the neurological event." Moreover, because that signal is compared to the detected signals, Pless meets the limitation requiring the processing unit to be configured to compare the target and detected signals.

Therefore, because we agree with the Examiner that Pless discloses all of the limitations of claim 1, we affirm the Examiner's anticipation rejection of that claim. Because they were not argued separately, claims 2-15, 20-21, 26-39, 48-50, 54, 58, 59-61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

Claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless in view of Abraham-Fuchs (Ans. 9-10).

As an alternative to the anticipation rejection over Pless, the Examiner cites Abraham-Fuchs as disclosing a method of detecting neurological events by comparing detected signals with a previously detected template signal indicative of a neurological event, and concludes that "it would have been obvious to provide [sic, practice] Pless' invention by comparing a

detected signal to a previously detected template signal indicative of activity preceding a neurological event to allow recognition of pathologies with high patient-to-patient variability" (Ans. 10).

Appellants argue that the alternative obviousness rejection amounts to an admission on the part of the Examiner that Pless does not teach the claimed target signal (App. Br. 19; *see also* Reply Br. 6-7). Appellants further argue that Abraham-Fuchs does not remedy Pless' failure to disclose a previously detected target signal indicative of activity that precedes a neurological event (App. Br. 19-21).

We are not persuaded by these arguments. As discussed above, we agree with the Examiner that Pless meets all of the limitations of claim 1. It is well settled that "'anticipation is the epitome of obviousness.'" *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). We therefore affirm the Examiner's obviousness rejection of claim 1. Because they were not argued separately, claims 2-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 107 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless or Pless in view of Abraham-Fuchs (Ans. 10).

The Examiner concedes that Pless does not explicitly disclose causing the finger of a patient to move as recited in claim 107, but contends that Pless "does disclose applying stimulation to the median nerve" and that "it is well known in the art to apply a suprathreshold stimulation to nerves to cause movement" (*id.*). The Examiner concludes that one of ordinary skill in the art would therefore have considered it obvious "to modify the invention of Pless (or Pless in view of Abraham-Fuchs) by providing a

suprathreshold stimulation to the median nerve to induce movement of a finger to indicate impending seizure." (*Id.*)

Appellants present no argument regarding this rejection. Therefore, because we detect no deficiency in the Examiner's prima facie case of obviousness, we affirm the Examiner's rejection of claim 107.

Claims 22 and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pless, or Pless in view of Abraham-Fuchs, in view of Gliner (Ans. 10-11).

The Examiner concedes that neither Pless nor Abraham-Fuchs discloses providing a sensor in the implant to detect brain movement, as recited in claims 22 and 84, and cites Gliner to meet that limitation (*id.* at 10). The Examiner concludes that one of ordinary skill in the art would have considered it obvious "to provide Pless' (or Pless in view of Abraham-Fuchs) invention with a movement sensor to more accurately detect seizure activity" (*id.* at 10-11).

Appellants present no argument regarding this rejection. Therefore, because we detect no deficiency in the Examiner's prima facie case of obviousness, we affirm the Examiner's rejection of claims 22 and 84.

SUMMARY

We affirm the Examiner's rejection of claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59-61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 under 35 U.S.C. § 102(b) as anticipated by Pless.

We affirm the Examiner's rejection of claims 1-15, 20-21, 26-39, 48-50, 54, 58, 59, 61, 63-77, 82, 83, 88-99, 105, 106, 108-111, 115, and 119-126 under 35 U.S.C. § 103(a) as obvious over Pless in view of Abraham-Fuchs.

We affirm the Examiner's rejection of claim 107 under 35 U.S.C. § 103(a) as obvious over Pless or Pless in view of Abraham-Fuchs.

We affirm the Examiner's rejection of claims 22 and 84 under 35 U.S.C. § 103(a) as being obvious over Pless, or Pless in view of Abraham-Fuchs, in view of Gliner.

AFFIRMED

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